OIPE IAP54 JAN 04 2006 PATENT & TRADEMARK OFFICE

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TRANSMITTAL OF APPEAL BRIEF

Docket No. 341148005US

In re Application of: Gisselberg et al.

Application No.	Filing Date	Examiner	Group Art Unit
09/954,700-Conf. #8619	September 14, 2001	S. Huang	2632

Invention: MINIATURE RESONATING MARKER ASSEMBLY

TO THE COMMISSIONER OF PATENTS:

Transmitted herewith is the Appeal Brief in this application, with respect to the Notice of Appeal filed: October 4, 2005 .

The fee for filing this Appeal Brief is $ 250.00 .

[ ] Large Entity [X] Small Entity

[X] A petition for extension of time is also enclosed.

The fee for the extension of time is $ 60.00 .

[X] A check in the amount of $ 310.00 is enclosed.

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[ ] Payment by credit card. Form PTO-2038 is attached.

[X] The Director is hereby authorized to charge any additional fees that may be required or credit any overpayment to Deposit Account No. 50-0665 .
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Dated: January 4, 2006

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OIPE IAP54
JAN 04 2006
PATENT & TRADEMARK OFFICE

Docket No.: 341148005US
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Gisselberg et al.

Application No.: 09/954,700 Confirmation No.: 8619

Filed: September 14, 2001 Art Unit: 2632

For: MINIATURE RESONATING MARKER ASSEMBLY Examiner: S. Huang

APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

As required under 37 C.F.R. § 41.37(a), this brief is in furtherance of the Notice of Appeal in this application filed on October 4, 2005. The fees required under 37 C.F.R. § 41.20(b)(2), and any required petition for extension of time for filing this brief and fees therefore, are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

This brief contains items under the following headings as required by 37 C.F.R. § 41.37 and M.P.E.P. § 1206:

I. Real Party In Interest
II Related Appeals and Interferences
III. Status of Claims
IV. Status of Amendments
V. Summary of Claimed Subject Matter
VI. Grounds of Rejection to be Reviewed on Appeal
VII. Argument
VIII. Claims
Evidence
Related Proceedings
Appendix A Claims

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I. REAL PARTY IN INTEREST

The real party in interest for this appeal is Calypso Medical Technologies, Inc., which is the assignee of record.

II. RELATED APPEALS, INTERFERENCES, AND JUDICIAL PROCEEDINGS

There are no other appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

A. Total Number of Claims in Application

There are 25 claims pending in application.

B. Current Status of Claims

1. Claims canceled: Claims 28-39 were canceled during prosecution.
2. Claims withdrawn from consideration but not canceled: Claims 23 and 27 were withdrawn in response to a restriction requirement.
3. Claims pending: Claims 1-22 and 24-26 are pending in the application.
4. Claims allowed: None
5. Claims rejected: Claim 24 stands rejected under 35 U.S.C. § 102(b). Claims 1-22 and 24-26 stand rejected under various U.S.C. § 103(a) rejections.

C. Claims On Appeal

The claims on appeal are claims 1-22 and 24-26.

IV. STATUS OF AMENDMENTS

Applicant filed an Amendment After Final Rejection on May 4, 2005. No claims were added, amended, or canceled in the May 4th response.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The invention is related to locating devices, and more particularly to miniature resonating marker assemblies and methods of tuning the same. (Specification, ¶ 1.) Medical procedures often require locating and treating areas within a patient's body. (Specification, ¶ 2.) Imaging systems, including x-ray, MRI, CT, and ultrasound have been used to help locate areas or particular targets within the body. (Specification, ¶ 2.) While the imaging systems can be very useful in some situations, they can be limited to two-dimensional information and may be unusable or difficult to use in certain procedures to provide real-time three-dimensional location information about a target. (Specification, ¶ 2.)

Many medical procedures, such as non-invasive radiation therapy and minimally invasive surgical procedures, require precise location information about the target to minimize the extent of collateral damaged healthy tissue around the target. (Specification, ¶ 3.) Markers have been used to locate targets on and in a patient's body in preparation for a medical procedure. (Specification, ¶ 2.) One example includes the use of gold fiducials, which are solid, inert, metal beads that can be implanted in a patient at or near a tumor or other target that may be difficult to accurately detect using conventional imaging systems. (Specification, ¶ 2.) The fiducial markers are passive markers that are easy to detect with imaging systems such as an x-ray or ultrasound but the passive markers do not provide active real-time location information during a medical procedure. (Specification, ¶ 3.)

Active, implantable marker assemblies that generate a detectable signal have been used to locate a selected target or the like in real time. (Specification, ¶ 4.) Many of the active markers are implantable in a patient, but they are hard-wired to a power source or other equipment external from the patient. (Specification, ¶ 4.) Leadless active markers also referred to as "wireless" active markers have been developed to be implanted in a patient's body at or near a selected target, such as a tumor. (Specification, ¶ 5.)

One drawback of conventional, wireless active markers is that they are fairly large in order to provide a range of operating characteristics that allow the marker to be accurately located within the patient's body. (Specification, ¶ 6.) Larger active markers are required in order to provide the required signal strength for detection and must be tuned adequately enough so that the detection system can detect the marker's signal. (Specification, ¶ 6.) The large active markers, however, have drawbacks, including a reduced accuracy of determining the marker's precise location relative to a target, the degree of invasiveness needed to implant the markers in the body, and the costs of producing accurately tuned markers. (Specification, ¶ 6.)

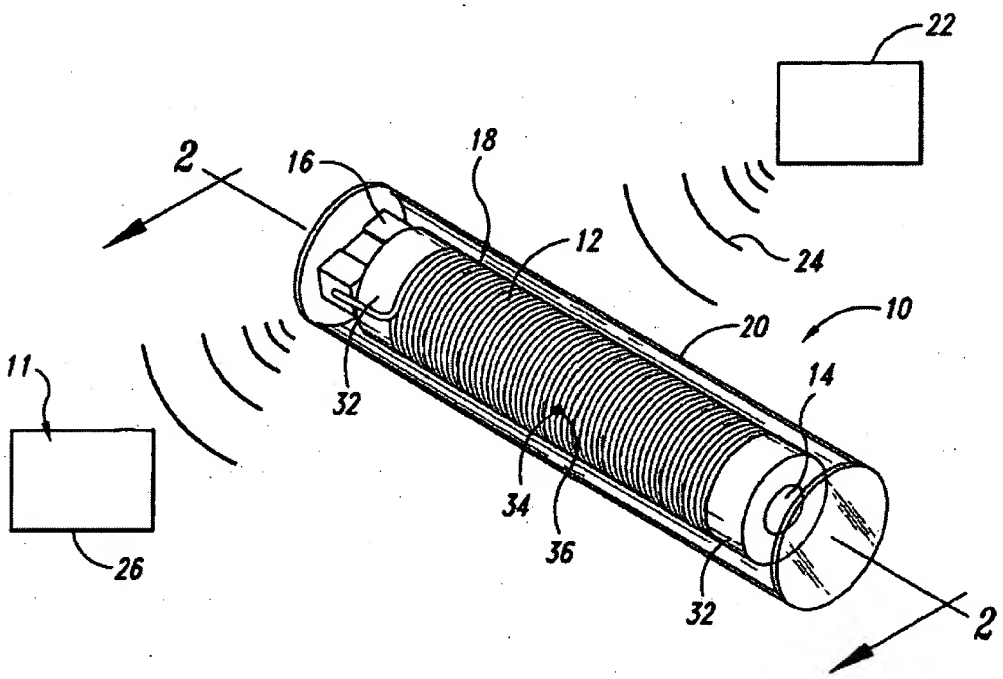


Fig. 1

Figure 1 – Current U.S. Application No. 09/954,700

Figure 1 of the pending application shows an implantable miniature resonating marker assembly 10 which overcomes the limitations and disadvantages of the prior art. (Specification, ¶ 36.) The marker assembly 10 is an inert, activatable assembly that can

be excited to generate a signal at a resonant frequency detectable by a marker detection system external to the patient. (Specification, ¶ 36.) The marker assembly 10 includes a coil 12 wound around a ferromagnetic core 14 to form an inductor. (Specification, ¶ 36.) The inductor is connected to a capacitor 16, so as to form a signal element 18. (Specification, ¶ 36.) Accordingly, the signal element 18 is an inductor (L) capacitor (C) series circuit. (Specification, ¶ 36.) The signal element 18 is enclosed and sealed in an encapsulation member 20 made of plastic, glass, or other inert material. (Specification, ¶ 36.) Accordingly, the marker assembly 10 is a fully contained and inert unit that can be used, as an example, in medical procedures in which the marker assembly is secured on and/or implanted in a patient's body. (Specification, ¶ 36.)

The marker assembly 10 can be activated by an external excitation source(s) 22, so the signal element 18 generates a detectable signal that allows the marker assembly to be precisely located, for example, during a medical procedure. (Specification, ¶ 37.) The excitation source 22, in one embodiment, generates a magnetic field 24 at a selected frequency that substantially matches the resonant frequency of the specifically tuned marker assembly 10. (Specification, ¶ 37.) When the marker assembly 10 is excited by the magnetic field 24, the signal element 18 generates a response signal at the resonant frequency 90 degrees out of phase with the magnetic field. (Specification, ¶ 37.) The marker assembly 10 is constructed to provide an appropriately "loud" and distinct signal by optimizing marker characteristics, such as the quality factor, for example, and by providing an accurate and precise means of tuning the marker to a predetermined frequency to allow reliable detection by the marker detection system 11. (Specification, ¶ 37.) The signal from the accurately tuned marker assembly 10 is sufficient to allow the marker detection system 11 to determine the marker assembly's identity, precise location, and orientation in three-dimensional space. (Specification, ¶ 37.)

The miniature marker assemblies 10 of the present application are accurately tuned to a chosen resonant frequency. (Specification, ¶ 38.) Because the miniature marker assemblies 10 are constructed to be very small, the markers must be tuned so that, when

energized, they will provide a response signal that is strong and clearly distinguishable from the excitation signal, signals from other markers, and environmental noise. (Specification, ¶ 38.) Accordingly, the signal will have a strength, clarity, and uniqueness that can be detected and analyzed by the sensor system 26 to determine the precise location of the marker assemblies 10 on and/or within the patient relative to the sensor system. (Specification, ¶ 38.) The information regarding the precise location and orientation of the marker assemblies 10 and the target areas is then usable to help minimize collateral damage to healthy tissues around the targets during radiation therapy, surgical procedures, or other selected medical procedures that require locating and tracking a specific tissue or area for monitoring or treatment purposes. (Specification, ¶ 38.)

The elongated cylindrical marker assembly 10 of the illustrated embodiment has a geometric center point 34. (Specification, ¶ 45.) The geometric center point 34 can be determined by locating the midpoint along each of the marker assembly's length, width, and depth. (Specification, ¶ 45.) A user can determine the geometric center point 34 of an implanted marker assembly 10 if needed by taking an image of the assembly with an x-ray or ultrasound device and physically measuring the image of the assembly. (Specification, ¶ 45.) The spatial relationship of the geometric center point 34 relative to the target or other marker assemblies 10 may also be visually identified.

The signal element 18 in the marker assembly 10 also generates a magnetic field when the signal element is excited, and the magnetic field has a magnetic center point 36. (Specification, ¶ 46.) If the core 14 was a symmetrical member about the X, Y, and Z axis, the endcaps 32 would be the same size, and the magnetic center point 36 would be offset from the marker assembly's geometric center point 34. (Specification, ¶ 46.) The core 14 of the illustrated embodiment, however, is an asymmetric core with endcaps 32 having different thicknesses. (Specification, ¶ 46.) The core 14 is shaped and sized so that the magnetic center 36 of the signal element 18 is coincident with the geometric center 34 of the marker assembly 10. (Specification, ¶ 46.)

The asymmetric configuration of the core 14 effectively shifts the center of the magnetic field axially along the length of the core. (Specification, ¶ 47.) The signal element 18 can be configured and positioned in the encapsulation member 20 so that the geometric and magnetic centers 34 and 36 are coincident with each other. (Specification, ¶ 47.) The coincident orientation of the geometric and magnetic centers 34 and 36 allows a physician or technician to nonvisually determine the precise location of an implanted marker assembly 10 relative to a target during a medical procedure. (Specification, ¶ 47.)

As an example, the marker assembly 10 can be permanently implanted in a patient and located visually with an imaging system to determine the marker assembly's position and location relative to the target before initiating a selected medical procedure. (Specification, ¶ 48.) The physician or technician can visually determine the marker assembly's geometric center 34 relative to the target. (Specification, ¶ 48.) The information about the geometric center 34 relative to the target can be utilized to provide patient set-up procedures or a treatment plan. (Specification, ¶ 48.) The physician or technician will know that, when the marker assembly 10 is excited via the excitation source 22 (Figure 1) and the location of the magnetic center 36 is nonvisually determined in three-dimensional space, the magnetic center is at the same location as the geometric center 34 and has the same relative orientation to the target. (Specification, ¶ 48.) Accordingly, the marker assembly 10 can provide extremely accurate nonvisual information regarding the marker assembly's actual real time location within the patient's body relative to the target. (Specification, ¶ 48.) That location information can be used to minimize the margins needed around the target when performing a medical procedure. (Specification, ¶ 48.) If the geometric center point 34 and the magnetic center point 36 are displaced by even small amounts, the margins around the target may need to be larger, thereby potentially having a greater impact on healthy tissue around the target. (Specification, ¶ 48.) Because both position errors that occur during imaging (geometric center) or during marker magnetic localization (magnetic center) affect target accuracy, coincident magnetic and geometric centers are a key attribute for implanted miniature marker assemblies.

A. Claim 1

One embodiment of a miniature resonating marker assembly set forth in claim 1 includes a single element comprising a core, a wire coil disposed around the core, and a capacitor connected to the wire coil. The signal element generates a magnetic field with a selected resonant frequency in response to a specific stimulus, and the magnetic field has a magnetic center along a first axis of the core. An inert encapsulation member encapsulates the signal element; the encapsulation member and the signal element define a unit having selected geometric shape. The selected geometric shape has a geometric center, wherein the geometric center is coincident with the magnetic center along at least the first axis of the core.

B. Claim 19

Another embodiment of a miniature resonating marker assembly having a geometric center set forth in claim 19 includes a core having an elongated central portion, a first cap having a first thickness, and a second cap having a second thickness. A wire coil is disposed around the central portion of the core between the first and second caps, and a capacitor is connected to the wire coil. The capacitor is operative to form a signal element that generates a magnetic field with a selected resonant frequency in response to a specific stimulus. The first cap is movable relative to the coil and capacitor for tuning the marker assembly to a selected resonant frequency.

C. Claim 20

Still another embodiment of a resonating marker assembly having a geometric center set forth in claim 20 includes a magnetic core having an elongated central portion, a wire coil, and a capacitor. The magnetic core has a first and second magnetic end cap opposite the central portion. The core is substantially symmetrical about a longitudinal axis of the core and is asymmetrical about a lateral axis of the core. The wire coil is disposed around the central portion of the magnetic core intermediate the first and second end caps. The capacitor is connected to the wire coil to form a single element that

generates a magnetic field with a selected resonant frequency in response to a specific stimulus. The magnetic field has a magnetic center along the first axis coincident with the geometric center of the resonating marker assembly.

D. Claim 21

Yet another embodiment of a resonating marker assembly having a geometric center set forth in claim 21 includes a core, a wire coil, and a capacitor. The core has an elongated central portion and first and second end caps connected to the central portion. The wire coil is disposed around the central portion of the core intermediate the first and second end caps. The capacitor is connected to the wire coil to form a tuned signal element that generates a magnetic field with a selected resonant frequency in response to a specific stimulus. The first end cap is movable relative to the coil and capacitor for tuning the marker assembly to a selected resonant frequency.

E. Claim 22

Yet another embodiment of a resonating marker assembly set forth in claim 22 includes a sleeve, a core, a wire coil, and a capacitor. The core has a central portion extending through the sleeve and further includes a pair of end caps connected to the central portion. The sleeve is between the end caps and the core is axially movable relative to the sleeve. The wire coil is disposed around the sleeve. The capacitor is connected to the wire coil and is proximate to the core to form a signal element that generates a magnetic field with a selected resonant frequency in response to a specific stimulus. The core is axially movable relative to the sleeve and the coil for tuning the marker assembly to a selected resonant frequency.

F. Claim 24

Yet another embodiment of a resonating marker assembly set forth in claim 24 includes a ferromagnetic core, a wire coil, a capacitor, and an axially adjustable segment. The ferromagnetic core has a first and second end, and the wire coil is disposed around the ferromagnetic core. The capacitor is positioned at the first end of the core and

operatively connects to the wire coil to form a signal element that generates a magnetic field with a selected resonant frequency in response to a specific stimulus. The axially adjustable segment at the second end of the core projects outwardly with respect to the longitudinal axis of the core.

G. Claim 25

Yet another embodiment of a resonating marker assembly set forth in claim 25 includes a core, a wire coil, a capacitor, and an inert encapsulation member. The core has a central portion intermediate to a pair of enlarged end caps, the central portion has a first magnetic permeability and the enlarged end caps have a second magnetic permeability different than the first magnetic permeability. The wire coil is disposed around the core and intermediate to the end caps. The capacitor is operatively connected to the wire coil to form a signal element that generates a magnetic field with a selected resonant frequency in response to a specific stimulus. The inert encapsulation member encapsulates the core, the wire coil, and the capacitor to form an activatable unit implantable in a patient through an introducer needle.

H. Claim 26

Yet another embodiment of a resonating marker assembly set forth in claim 26 includes a capacitor, an elongated ferromagnetic core, a wire coil and an inert encapsulation member. The capacitor has an aperture therethrough, and the elongated ferromagnetic core extends through the aperture in the capacitor. A wire coil is connected to the capacitor, the wire coil has a first portion disposed around the core adjacent to one side of the capacitor, and a second portion disposed around the core adjacent to another side of the capacitor. The inert encapsulation member encapsulates the capacitor, the core, and the coil.

VI. GROUNDS OF OBJECTION TO BE REVIEWED ON APPEAL

(A) Claim 24 stands rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,618,822 to Hansen ("Hansen");

(B) Claims 1-3 and 12 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 3,836,842 to Zimmermann et al. ("Zimmermann");

(C) Claims 4-9 and 15-18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Zimmermann in view of U.S. Patent No. 5,211,129 to Taylor et al. ("Taylor") or U.S. Patent No. 6,400,338 to Mejia et al. ("Mejia");

(D) Claims 10 and 11 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Zimmermann in view of Taylor or Mejia as applied to claims 1 and 4-8, and in further view of U.S. Patent No. 6,441,741 to Yoakum ("Yoakum");

(E) Claims 13 and 14 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Zimmermann in view of Yoakum;

(F) Claims 20 and 26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Mejia;

(G) Claim 21 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Mejia in view of Yoakum;

(H) Claim 22 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Yoakum in view of Taylor or Mejia;

(I) Claim 19 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Mejia in view of Hansen; and

(J) Claim 25 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,087,791 to Lemberger ("Lemberger") in view of Taylor.

VII. ARGUMENT

Anticipation under 35 U.S.C. § 102 requires:

> A person shall be entitled to a patent unless -
>
> . . .
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or
>
> . . .

The individual reference must teach every aspect of the claimed invention either explicitly or impliedly. (M.P.E.P. § 706.02.) The propriety of the current rejection of claim 24 under Section 102 depends on a proper interpretation of claim 24 and an accurate characterization of Hansen. For the reasons explained below, the Examiner's interpretation of claim 24 is inconsistent with the meaning of several terms set forth in this claim, and the characterization of Hansen set forth in the final Office Action is inaccurate in light of the teachings of Hansen.

Anticipation under 35 U.S.C. § 103(a) requires:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

"[T]he [E]xaminer bears the initial burden of presenting a *prima facie* case of obviousness." *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d (BNA) 1955, 1956 (Fed. Cir. 1993). "'A *prima facie* case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art.'" *Id.* (quoting *In re Bell*, 991 F.2d 781, 782, 26 U.S.P.Q.2d (BNA) 1529, 1531 (Fed. Cir. 1993)).

To establish a *prima facie* case of obviousness, the Examiner must (1) identify prior art references that disclose all the elements of the claims, and (2) provide a suggestion or motivation to modify the references to produce the claimed invention. M.P.E.P. § 2143. With respect to the second requirement, the Examiner must provide a suggestion or motivation to combine from within the prior art, and may not rely upon hindsight gleaned from applicants' invention itself. *See, e.g., Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1050-51, 5 U.S.P.Q.2d (BNA) 1434, 1438 (Fed. Cir. 1988).

Under these standards, applicants' invention would not have been obvious. The Examiner has not identified prior art references that disclose all the elements of the pending claims. The Examiner also has not provided any motivation from within the prior art to modify the cited references so as to produce the claimed invention.

A motivation or suggestion to combine must come from the prior art. *In re Zurko,* 258 F.3d 1379, 1385-86, 59 U.S.P.Q.2d (BNA) 1693, 1697 (Fed. Cir. 2001); *In re Rijckaert*, 9 F.3d at 1532, 28 U.S.P.Q.2d (BNA) at 1956. The Examiner has not pointed to any teaching or suggestion within the prior art that supports his conclusory statements about a motivation or suggestion to combine. Rather, the Examiner's statements are a classic—and legally impermissible—use of hindsight. The Examiner recognizes some of the improvements contributed by applicants' invention, and attempts to attribute those improvements to some sort of common sense or background knowledge available to anyone of ordinary skill in the art at the time of the invention. The Federal Circuit has consistently held that reliance on such common sense or basic knowledge is impermissible. *Id.*; *see also In re Sang Su Lee*, 277 F.3d 1338, 61 U.S.P.Q.2d (BNA) 1430 (Fed. Cir. 2002). No teaching or motivation from within the prior art suggested combining the cited art, and the Examiner's conclusory statements are insufficient. The pending claims should be allowed.

Furthermore, if the Examiner suggests that an element of the claim is inherent in the prior art the Examiner must provide rationale or evidence tending to show inherency. M.P.E.P. § 2112. The fact that a certain result or characteristic may occur or be present in

the prior art is not sufficient to establish the inherency of that result or characteristic. M.P.E.P. § 2112 (citing *In re Rijckaert*, 9 F.3d 1531, 1534, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 U.S.P.Q. 323, 326 (CCPA 1981)). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." M.P.E.P. § 2112 (citing *In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q.2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) (The claims were drawn to a disposable diaper having three fastening elements. The reference disclosed two fastening elements that could perform the same function as the three fastening elements in the claims. The court construed the claims to require three separate elements and held that the reference did not disclose a separate third fastening element, either expressly or inherently.)). Also, "[a]n invitation to investigate is not an inherent disclosure" where a prior art reference "discloses no more than a broad genus of potential applications of its discoveries." M.P.E.P. § 2112 (citing *Metabolite Labs, Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367, 71 U.S.P.Q.2d 1081, 1091 (Fed. Cir. 2004) (explaining that "[a] prior art reference that discloses a genus still does not inherently disclose all species within that broad category" but must be examined to see if a disclosure of the claimed species has been made or whether the prior art reference merely invites further experimentation to find the species).

"In relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." M.P.E.P. § 2112 (citing *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original) (Applicant's invention was directed to a biaxially oriented, flexible dilation catheter balloon (a tube which expands upon inflation) used, for example, in clearing the blood vessels of heart patients. The Examiner applied a U.S. patent to

Schjeldahl which disclosed injection molding a tubular perform and then injecting air into the perform to expand it against a mold (blow molding). The reference did not directly state that the end production balloon was biaxially oriented. It did disclose that the balloon was "formed from a thin flexible inelastic, high tensile strength, biaxially oriented synthetic plastic material." *Id.* at 1462 (emphasis in original). The Examiner argued that Schjeldahl's balloon was inherently biaxially oriented. The Board reversed on the basis that the Examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.)). M.P.E.P. § 2112 goes on to state "[A] finding of anticipation requires that all aspects of the claimed invention were already described in a single reference: a finding that is not supportable if it is necessary to prove facts beyond those disclosed in the reference in order to meet the claim limitations." M.P.E.P. § 2112 (citing *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991); *see also Standard Havens Products, Inc. v. Gencor Industries, Inc.*, 953 F.2d 1360, 1367 (Fed. Cir. 1991)).

A. Response to Section 102 Rejection of Claim 24 (Hansen)

Independent claim 24 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Hansen. For the reasons explained below, this rejection is not proper because the cited reference does not disclose or suggest all of the claimed features.

1. Claim 24 is Directed to a Resonating Marker Assembly Including, *Inter Alia*, a Ferromagnetic Core and an Axially Adjustable Segment that Projects Outwardly with Respect to a Longitudinal Axis of the Core

Independent claim 24 is directed to a resonating marker assembly including a ferromagnetic core having a first end and a second end. A wire coil is disposed around the core between the first and second ends, and a capacitor is connected to the wire coil. The core, coil, and capacitor form a signal element that, when energized, generates a magnetic field at a selected resonating frequency. The marker assembly further includes an axially adjustable segment at the second end of the core that projects outwardly with respect to the longitudinal axis of the core.

2. Hansen is Directed to a Displacement Sensing Device Including Adjustable Tuned Circuitry

Hansen discloses a displacement sensing device including adjustable tuned circuitry to calculate the displacement between two objects with respect to each other.

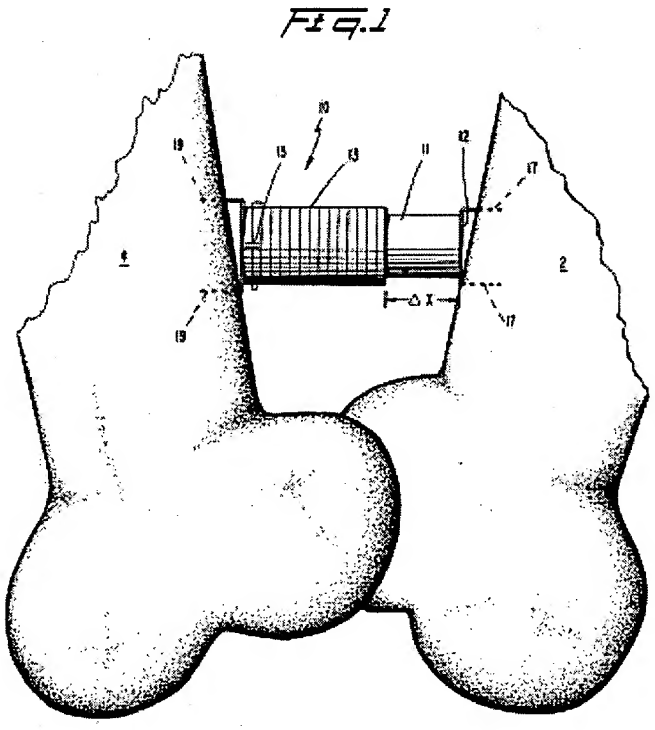


Figure 1 – U.S. Patent No. 4,618,822 (Hansen)

Referring to Figure 1 Hansen, this reference discloses a sensor 10 including a ferrite rod 11, a coil 13, and a capacitor 15 connected to the coil 13. The coil 13 is positioned about the rod 11 so that the rod 11 can reciprocate within the coil 13. The sensor 10 further includes (a) a first set of hooks 17 at a free end 12 of the rod 11 to connect the sensor 10 to a first object (e.g., a bone 2), and (b) a second set of hooks 19 at the opposite end of the rod 11 to connect the sensor 10 to a second object (e.g., a bone 4). As the bones 2 and 4 move relative to each other, the rod 11 can reciprocate within the coil 13, resulting in a relative change in the resonant frequency of the sensor 10.

3. Claim 24 is Allowable Over Hansen Because this Reference Fails to Teach or Suggest an Axially Adjustable Segment at the Second End of the Core that Projects Outwardly With Respect to the Longitudinal Axis of the Core

Claim 24 is patentable over Hansen under Section 102 because this reference fails to teach or suggest an "axially adjustable segment at the second end of the core that projects outwardly with respect to the longitudinal axis of the core." In contrast, Hansen discloses a single, unitary rod 11 that moves or reciprocates relative to the coil 13. Nowhere does Hansen teach or suggest a separate "axially adjustable segment" at the free end 12 of the rod 11. Instead, Hansen teaches that the rod 11 is fixed to the bones 2 and 4 with the first and second set of hooks 17 and 19, respectively, so that as the bones 2 and 4 move relative to each other, the entire rod 11 moves relative to the coil 13. Accordingly, Hansen does not disclose at least one element of claim 24 and the Section 102 rejection should be withdrawn.

B. Response to Section 103 Rejection of Claims 1-3 and 12 (Zimmermann)

Claims 1-3 and 12 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Zimmermann. The Examiner asserts that (a) Figure 1b of Zimmermann discloses a marking device having coincident geometric and magnetic centers, and (b) a miniature version of the marking device of Zimmermann "with smaller size electrical elements that provides a shorter communication range is do-able." (Office Action, p. 3-4.) For the reasons explained below, however, applicants respectfully disagree with the Examiner.

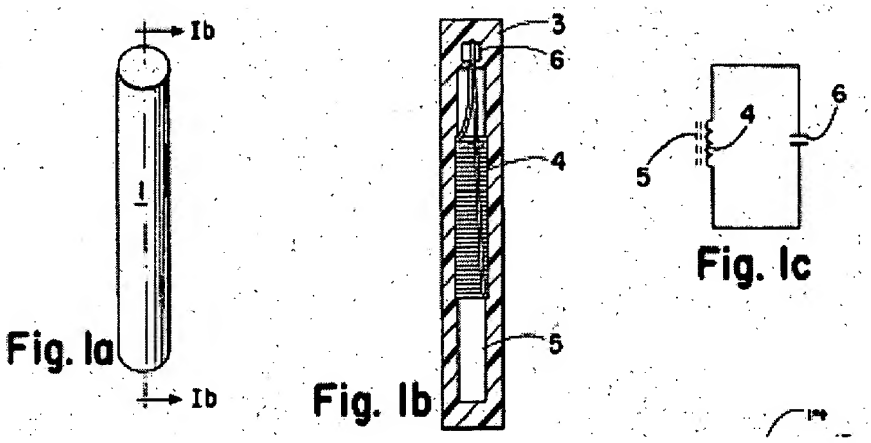
1. Independent Claim 1 is Directed to a Miniature Resonating Marker Assembly Including, *Inter Alia*, a Signal Element Having a Core, a Wire Coil Around the Core, a Capacitor Connected to the Wire Coil, and an Inert Encapsulation Member Encapsulating the Signal Element

Independent claim 1 is directed to a miniature resonating marker assembly. The miniature resonating marker assembly includes a core, a wire coil disposed around the core, and a capacitor connected to the wire coil adjacent to the magnetic core. The core, coil, and capacitor form a signal element that generates a magnetic field at a selected

resonating frequency in response to a wirelessly transmitted source field. The magnetic field has a magnetic center point positioned along a first axis of the core. An inert encapsulation member encapsulates the signal element and defines a geometric shape of the resonating marker assembly. The geometric shape has a geometric center point substantially coincident with the magnetic center point along at least a first axis of the signal element. Accordingly, when a user locates the marker assembly's magnetic center point, the user will have also located the marker assembly's geometric center point. Conversely, when a user locates the marker assembly's geometric center, the user will have also located the marker assembly's magnetic center point.

2. Zimmermann is Directed to a Passive Marking Device for Placement in a Location Such that the Location is Thereafter Identifiable with a Suitable Interrogating Instrument

Zimmermann discloses a passive marking device 1 for marking a location underground and a suitable interrogating instrument 100 used to find the buried marking device. Zimmermann is silent with regard to the issue of geometric and magnetic alignment.



Figures 1a-1c – U.S. Patent No. 3,836,842 (Zimmermann)

Referring to Figures 1a-1c of Zimmermann, the marking device 1 includes a coil 4 of insulated conductor wire placed on an elongated ferrite core 5. A capacitor 6 is connected in parallel with the coil 4. The core 5 is 1 cm in diameter and 20 cm in length. The

marking device 1 is tuned by adjusting the longitudinal position of the coil 4 on the core 5 such that the marking device has a resonant frequency of 62.5 KHz. (Zimmermann, col. 6, lns. 3-11.) The marking device 1 also includes a rigid encapsulation 3 formed from a thermosetting epoxy material that will break or shatter along with the core 5 if the marking device 1 is subjected to a mechanical shock. (Zimmermann, col. 6, lns. 24-29.) As seen in Figure 6, the interrogating instrument 100 includes (a) a generating portion that generates a continuous wave magnetic field, and (b) a detecting portion that detects a fluctuating magnetic field. The presence of the marking device 1 is indicated when the interrogating instrument 100 detects the magnetic field resulting from the resonance of the marking device during interruptions in the field from the generating portion. The interrogating instrument 100 can find the position of the buried marking device 1 to within an area of approximately two inches or less. (Zimmermann, col. 13, lns. 43-44.)

3. Claim 1 is Allowable over Zimmermann Because this Reference Does Not Teach or Suggest all of the Claimed Features and is Fundamentally Flawed for Use with Very Small Transmitters in Human Patients

Claim 1 is patentable over Zimmermann under Section 103 because (a) the cited reference does not disclose or suggest all of the claimed features, and (b) a person skilled in the art would not be motivated to modify Zimmermann's marking devices for markers used in human patients. Claim 1, for example, recites that the marker assembly includes a magnetic center point positioned along the first axis of the core and a geometric center point substantially coincident with the magnetic center point. Nowhere does Zimmermann teach or suggest this feature. The Examiner asserts that Figure 1b of Zimmermann appears to show coincidence between the geometric center and the magnetic center of the marking device. (Office Action, p. 3.) This is not correct. Referring to Figure 1b of Zimmermann, the marking device 1 has a geometric center at approximately a center portion of the device. On the other hand, the capacitor 6 in the marking device 1 is spaced apart from the core 5 and the coil 4 at one end of the device. More specifically, because the core 5, coil 4 and capacitor 6 all affect the magnetic center, the longitudinal offset of the capacitor 6 shifts the magnetic center of Zimmermann's device axially along the length

of the core away from the geometric center of the device. Furthermore, the position of the relevant electrical components in Zimmermann (i.e., the coil 4, core 5, and capacitor 6) are fixed with respect to one another within the encapsulant 3 after tuning the device to 62.5 KHz such that the magnetic center cannot be moved or adjusted to be coincident with the geometric center. Accordingly, the magnetic center of Zimmermann's device is not coincident with the geometric center.

The M.P.E.P. states that "[o]bviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the reference[s] themselves or in the knowledge generally available to one of ordinary skill in the art." (M.P.E.P. § 2143.01; emphasis added.) The M.P.E.P. further states that the mere fact that a reference can be modified does not render the resultant combination obvious "unless the prior art also suggest the desirability of the combination." (*Id.*; emphasis added.) Here, the Examiner fails to cite any prior art that suggests the desirability of modifying the device of Zimmermann to have coincidence between the geometric center and the magnetic center of the marking device. Zimmermann's device, in use, does not require such precision and by teaching a longitudinal offset of the capacitor, Zimmermann appears to teach away from such a modification. There is no need or motivation to align the magnetic and geometric centers of Zimmermann's device and, accordingly, the Section 103 rejection of claim 1 over Zimmermann should be withdrawn.

Although the Examiner concedes that the marking device of Zimmermann may not have coincident geometric and magnetic centers, the Examiner attempts to overcome this shortcoming on the grounds that, depending on the desired resonating frequency, "the position of the coil [4] or number of windings over the core [5] can be different which leads to the possibility of coinciding the magnetic center and geometric center" as required by claim 1. (Office Action, p. 12.) This reasoning by the Examiner directly opposes Zimmermann's explicit teaching that the longitudinal position of the coil 4 is adjusted relative to the core 5 to tune the marking device to a frequency of 62.5 KHz, after which the marking device 1 is encapsulated with an encapsulating material, to making any further

adjustments generally impossible. Therefore, it would not have been obvious (or even possible) to modify the arrangement of the coil 4 or number of windings over the core 5 in Zimmermann's marking device 1 to come up with the claimed combination of elements. Thus, the Examiner is incorrect in suggesting that the coincident geometric and magnetic center element of the claim is inherent in Zimmermann, as the Examiner has failed to provide a basis in fact and/or technical reasoning to support this conclusion.

Claim 1 is further patentable over Zimmermann under Section 103 because a person skilled in the art would not be motivated to modify or otherwise use Zimmermann's passive marking device for use in human patients. As mentioned previously, the Examiner asserts that miniaturizing Zimmermann's marking device with smaller components is "do-able" and, accordingly, it would have been obvious to one skilled in the art to modify Zimmermann's marking device in such a way. For at least the reasons explained below, however, the Examiner's assertions are not correct.

Zimmermann is fundamentally flawed for use with very small transmitters in human patients. More specifically, although Zimmermann teaches a system for locating an object using a magnetic field, a person skilled in the art would have recognized the difficulties in miniaturizing Zimmermann's marker for use in a human to perform medical procedures. The field strength of an alternating current magnetic transponder is, in part, a function of the number of windings in the coil and the size and material of the core. The field strength for a marking device having a diameter as claimed would be extremely small and difficult to distinguish.

This gives rise to several problems not faced by miniaturizing the very large marker of Zimmermann. First, to induce enough voltage in the circuit of such a small marking device, the interrogating instrument must generate a magnetic field several orders of magnitude larger than that of the marking device's field. Second, such large source fields drown out the signal from the small markers. Third, even if the marker signal is detected, it is so small that it is subject to noise in the field. Zimmermann does not face these challenges, and Zimmermann also does not have the concerns of implanting a marker in a

human. Moreover, Zimmermann teaches that the interrogating instrument generates a continuously magnetic wave which would likely interfere with the signal from a marker configured to be implanted in a patient. As a result, the location of small implantable marking devices computed by Zimmermann's system would be unreliable and subject to errors. A person skilled in the art would thus be deterred from reducing the size of Zimmermann's device to the claimed size of the marking assembly. Claim 1 is accordingly patentable over Zimmermann under Section 103 for this additional reason because it would not have been obvious at the time of the invention to modify the passive marking device of Zimmermann to be contained within a miniature biocompatible body to be implanted into a human patient.

Additionally, claim 12 is allowable for the reasons set forth above and also because claim 12 further includes a geometric center coincident with the magnetic center along three axes of the unit. In contrast, the interrogating instrument of Zimmermann senses the proximity of the marker relative to the instrument. Assuming an adequate marker signal relative to environmental noise, an instrument that uses a single inductive sensor to detect the presence of marker is fundamentally incapable of marker localization in three-dimensional space. A single sensor instrument such as Zimmermann is only capable of providing a relative distance indication for the distance from the marker to the instrument. Such an instrument would not provide a coincident geometric and magnetic center along three axes of the unit as claimed.

Similarly, claims 2 and 3 are allowable as depending from allowable base claim 1, and also because of the additional features of these dependent claims. Accordingly, the Section 103 rejection of claims 2, 3, and 12 should be withdrawn.

C. Response to Section 103 Rejection of Claims 4-9 and 15-18 (Zimmermann, Taylor, Mejia)

Claims 4-9 and 15-18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Zimmermann in view of Taylor or Mejia. Claims 4-9 and 15-18 depend from base claim 1. As discussed above, Zimmermann fails to disclose or suggest all the

features of claim 1. Taylor and Mejia fail to cure the above-noted deficiencies of Zimmermann to support a Section 103 rejection of claim 1. Accordingly, dependent claims 4-9 and 15-18 are allowable over Zimmermann, Taylor, and Mejia for at least the reason that these references, either alone or in combination, fail to disclose or suggest the features of claim 1 and the additional features of claims 4-9 and 15-18. Therefore, the Section 103 rejection of dependent claims 4-9 and 15-18 should be withdrawn.

D. Response to the Section 103 Rejection of Claims 10 and 11 (Zimmermann, Taylor, Mejia, Yoakum)

Claims 10 and 11 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Zimmermann in view of Taylor or Mejia, and in further view of Yoakum. Claims 10 and 11 depend from base claim 1. As discussed above, Zimmermann fails to disclose or suggest all the features of claim 1. Taylor, Mejia, and Yoakum fail to cure the above-noted deficiencies of Zimmermann to support a Section 103 rejection of claim 1. Accordingly, dependent claims 10 and 11 are allowable over Zimmermann, Taylor, Mejia, and Yoakum for at least the reason that these references, either alone or in combination, fail to disclose or suggest the features of claim 1 and the additional features of claims 10 and 11. Therefore, the Section 103 rejection of dependent claims 10 and 11 should be withdrawn.

E. Response to the Section 103 Rejection of Claims 13 and 14 (Zimmermann and Yoakum)

Claims 13 and 14 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Zimmermann in view of Yoakum. Claims 13 and 14 depend from base claim 1. As discussed above, Zimmermann fails to disclose or suggest all the features of claim 1. Yoakum fail to cure the above-noted deficiencies of Zimmermann to support a Section 103 rejection of claim 1. Accordingly, dependent claims 13 and 14 are allowable over Zimmermann and Yoakum for at least the reason that these references, either alone or in combination, fail to disclose or suggest the features of claim 1 and the additional features of claims 13 and 14. Therefore, the Section 103 rejection of dependent claims 13 and 14 should be withdrawn.

F. Response to the Section 103 Rejection of Claims 20 and 26 (Mejia)

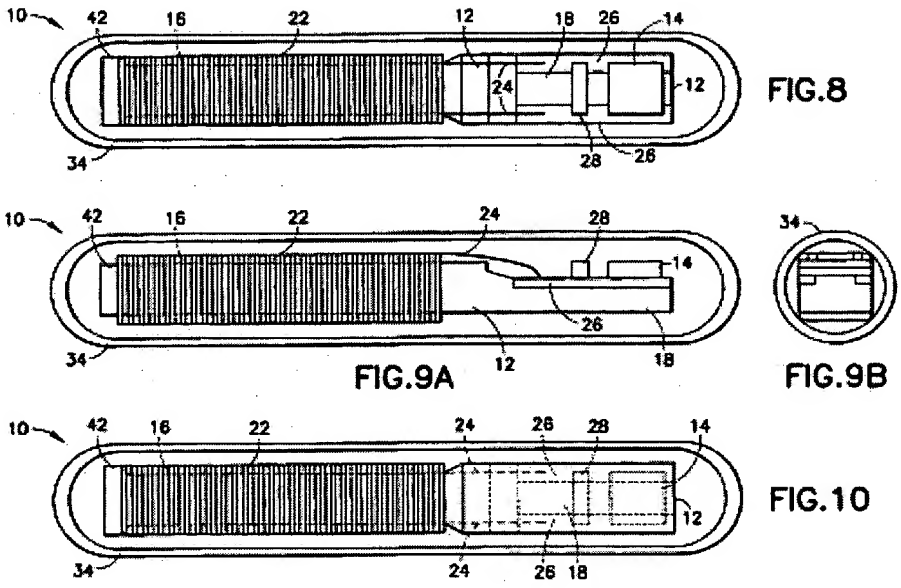
Claims 20 and 26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Mejia. For the reasons explained below, this rejection is not proper because the applied reference fails to disclose or suggest all the claimed features.

1. Claim 20 is Directed to a Miniature Resonating Marker Assembly Having a Geometric Center Coincident with the Assembly's Magnetic Center

Independent claim 20 is directed to a miniature resonating marker assembly including a ferromagnetic core having an elongated central portion and first and second ferromagnetic endcaps at opposite ends of the central portion. The core is substantially symmetrical about a longitudinal axis of the core, but it is asymmetrical about a lateral axis of the core. A wire coil is disposed around the central portion of the core between the first and second endcaps, and a capacitor is connected to the wire coil. The core, coil, and capacitor form a signal element that, when energized, generates a magnetic field at a selected resonating frequency. The magnetic field has a magnetic center point positioned along a first axis coincident with the geometric center of the resonating marker assembly.

2. Mejia Discloses a Passive Integrated Transponder Tag Including a Unitary Antenna Core

Mejia teaches a passive integrated transponder (PIT) tag for implantation in laboratory animals, pets, or livestock.



Figures 8-10 – U.S. Patent No. 6,400,338 B1 (Mejia)

Referring to Figures 8-10 of Mejia, this reference discloses a PIT tag 10 having a unitary core 12 (i.e., a one-piece core) extending substantially the entire length of the tag 10 and an encapsulation means 34 encasing the core 12. The core 12 includes a coil forming portion 16 at one end of the core 12 and an integrated circuit (IC) support portion 18 at the other end of the core 12. The coil forming portion 16 includes a center portion 36 having beveled ends 40 leading to end portions 42. Wire is wound around the center portion 36 of the coil forming portion 16 to form a coil 20. The IC support portion 18 is a flattened plane that extends beneath and supports an integrated circuit 14 and a capacitor 28. The IC support portion 18 can further include metallization layers 26 to electrically couple the coil 20 to the integrated circuit 14 and capacitor 28. The capacitor 28 is an optional component that may be eliminated, as a matter of design choice, depending on the particular integrated circuit 14 used in a given PIT tag.

3. Claim 20 is Allowable Over Mejia Because this Reference Fails to Teach or Suggest a Magnetic Center Point Coincident with a Geometric Center Point

Claim 20 is patentable over Mejia under Section 103 because this reference fails to teach or suggest a magnetic center point coincident with the device's geometric center point. To the contrary, the magnetic center point of Mejia's PIT tag is not even close to its geometric center point. The Examiner correctly asserts that "Mejia does not disclose that the magnetic center along a first axis [is] coincident with the geometric center of [Mejia's tag]." (Office Action, p. 7.) The Examiner, however, incorrectly states that it is possible that the magnetic center and geometric center of Mejia's PIT tag can be coincident by "modifying the shape or configuration of the unitary core of Mejia" (e.g., removing the IC 14 altogether, changing the configuration of the IC support portion 18, the transition portion 44, and/or the end portions 42 of the core 12). (*Id.*)

The M.P.E.P. states that "[i]f a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." (M.P.E.P. § 2143.01; emphasis added.) Furthermore, "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." (*Id.*; emphasis added) The Examiner admits that the magnetic center is not at the geometric center of Mejia's PIT tag, and then tries to assert that it could be possible for the magnetic center and geometric center of the PIT tag to be coincident. Mejia does not teach or suggest this claimed feature, and a person skilled in the art would not be motivated to modify the structure of Mejia's PIT tag such that the geometric and magnetic centers of the device were coincident. The Examiner relies on several portions of Mejia that teach the configuration of the transition portion 44 and the integrated circuit support portion 18 of the PIT tag 10 can be different than that shown in the figures. (Mejia, col. 4, lns. 42-64.) Nowhere does Mejia teach or suggest, however, that the PIT tag 10 can be reconfigured such that the magnetic and geometric centers are coincident. In fact, the unitary, one-piece core 12 of Mejia does not allow for any major adjustment of the

magnetic center point. Elimination of the transition portion 44 and/or reconfiguration of the integrated circuit support portion 18 would not align the magnetic center point with the geometric center point of Mejia's PIT tag 10. Accordingly, the Section 103 rejection of claim 20 should be withdrawn.

4. Claim 26 is Directed to a Miniature Resonating Marker Assembly Including, *Inter Alia*, a Capacitor Having an Aperture Therethrough

Independent claim 26 is directed to a miniature resonating marker assembly including an elongated ferromagnetic core, a wire coil connected to the capacitor, and a capacitor having an aperture therethrough. The core extends through the aperture in the capacitor and the coil includes a first portion around the core on one side of the capacitor and a second portion around the core on the other side of the capacitor. An inert encapsulation member encapsulates the capacitor, coil, and core.

5. Claim 26 is Allowable Over Mejia Because this Reference Fails to Teach or Suggest a Capacitor Having an Aperture

Claim 26 is also patentable over Mejia under Section 103 because this reference fails to teach or suggest a capacitor having an aperture therethrough. The Examiner asserts that Mejia differs from the claimed invention "in that it does not disclose the specific arrangement/position of the capacitor, core and coil. However such specification is merely a matter of design choice on packaging and therefore an obvious modification to the assembly of Mejia." (Office Action, p. 8.) One of the primary inventive aspects of Mejia, however, is the specific arrangement of the coil forming portion 16 and the integrated circuit support portion 18. For example, Mejia teaches that the PIT tag "may be able to sustain more shock and vibration than conventional PIT tags because the integrated circuit support portion 18 physically supports the integrated circuit 14 and/or capacitor 28." (Mejia, col. 7, lns. 42-46.)

In contrast to Mejia, claim 26 teaches that the capacitor has an aperture therethrough and that the core extends through the aperture in the capacitor such that the first portion of the wire coil is on one side of the capacitor and the second portion of the coil

is on the other side of the capacitor. As mentioned previously, M.P.E.P. § 2143.01 states that if proposed modifications to the prior art invention would make the prior art invention unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. Here, it would be impracticable to modify Mejia's PIT tag in accordance with the claimed arrangement and destroy one of Mejia's primary inventive aspects. Accordingly, the Section 103 rejection of claim 26 over Mejia should be withdrawn.

G. Response to the Section 103 Rejection of Claim 21 (Mejia and Yoakum)

Claim 21 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Mejia in view of Yoakum. The Examiner asserts that it would have been obvious to modify the PIT tag of Mejia in light of Yoakum to make "one endcap adjustable/movable for positioning the coil over the core to tune the marker to the specific resonant frequency . . ." (Office Action, p. 8.) Claim 21 is patentable over Mejia and Yoakum under Section 103 because, as discussed above, modifying the unitary core 12 of Mejia in such a way would obviate one of the primary inventive aspects of Mejia. Furthermore, Mejia specifically discloses that the unitary core 12 is a "one-piece core." (Mejia, col. 2, ln. 55.) Accordingly, Mejia teaches away from including the movable endcap of claim 21. Moreover, Yoakum fails to cure the above-noted deficiencies of Mejia or provide sufficient motivation to modify Mejia's device. Accordingly, the Section 103 rejection of claim 21 should be withdrawn.

The Examiner cites Hansen to further support the assertion that the core 12 of Mejia could be modified to include the claimed features. The Examiner's characterization of Hansen, however, is incorrect. For example, the Examiner asserts that Hansen discloses "a movable endcap 12" and that a "change in the displacement of the endcap 12 provides a different resonant frequency from the marker 10." (Office Action, p. 14.) As discussed above, Hansen does not include a movable endcap. The core 11 of Hansen is a unitary rod that moves or reciprocates relative to the coil 13. The free end 12 of the core 11 is fixed to an object (e.g., the bone 2), and the entire core 11 moves relative to the coil 13 as the bone 2 itself moves. Nowhere does Hansen disclose or suggest the endcap of claim

21 that is "movable relative to the coil and capacitor for tuning the marker assembly to a selected resonant frequency." Accordingly, for at least this additional reason the Section 103 rejection of claim 21 should be withdrawn.

H. Response to the Section 103 Rejection of Claim 22 (Yoakum, Taylor, Mejia)

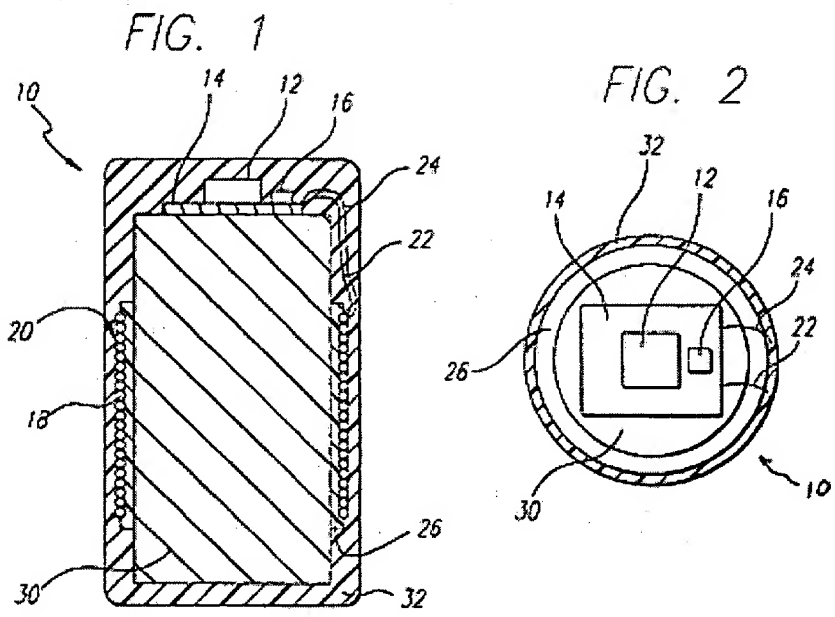
Claim 22 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Yoakum in view of Taylor or Mejia. The Examiner asserts that "it would have been obvious . . . to modify the core of Yoakum to include endcaps as taught by Taylor and Mejia so that the coil with the sleeve is securely positioned over the core to prevent variation in the marker's resonating frequency." (Office Action, p. 9.) For the reasons explained below, however, applicants respectfully disagree with the Examiner.

1. Claim 22 is Directed to a Miniature Resonating Marker Assembly Including, *Inter Alia*, an Elongated Plastic Sleeve with a Wire Coil Disposed on the Sleeve

Independent claim 22 is directed to a miniature resonating marker assembly having an elongated plastic sleeve with a wire coil disposed on the sleeve. A central portion of a ferromagnetic core extends through the sleeve and a pair of endcaps are connected to the central portion of the core so that the sleeve is positioned between the endcaps. A capacitor is operatively connected to the wire coil and positioned adjacent to the ferromagnetic core to form a signal element tunable to resonate at a selected frequency. The core is axially movable relative to the sleeve and the coil for tuning the marker assembly to have a selected inductance value.

2. Yoakum is Directed to a Transponder Over-Molded with an Injection Molding Material

Referring to Figures 1 and 2 of Yoakum, this reference discloses a transponder 10 having an integrated circuit 12 mounted on a circuit board 14 with a capacitor 16.



Figures 1 and 2 – U.S. Patent No. 6,441,741 B1 (Yoakum)

The integrated circuit 12 and capacitor 16 are electrically coupled to a wire 18 formed into a coil 20. The coil 20 is wrapped around a bobbin 26 and then positioned over a core 30. The circuit board 14 is affixed to an end of the core 30. Yoakum teaches that "a tuned transponder assembly 10 can be fabricated by moving the coil 20 axially along the long axis of the ferrite core 30 until a tuned inductor/capacitor system is established and then securing the bobbin 26 with coil 20 to the ferrite core 30 during the manufacturing process." (Yoakum, col. 4, lns. 53-57.) As shown in Figures 3-7 of Yoakum, the transponder 10 is then positioned within a molding tool 40 and over-molded with a plastic, polymeric, or epoxy injection molding material 32.

3. Claim 22 is Allowable Over the Applied References Because One Skilled in the Art Would Not Modify Yoakum's Transponder to Include Endcaps

Claim 22 is allowable over the applied references because it would not have been obvious to modify Yoakum's transponder to include endcaps. As explained above, Yoakum teaches that a circuit board 14 having an integrated circuit 12 and capacitor 16 is mounted on one end of the core 30. Thus, the claimed pair of endcaps connected to the

central portion of the core would conflict with the desired arrangement of Yoakum's device. Furthermore, one of the primary inventive aspects of Yoakum is the use of the molding tool 40 to encapsulate the transponder. The endcaps would interfere with the placement of the transponder in Yoakum's molding tool and thus hinder one of the primary teachings of Yoakum.

The Examiner further alleges that it would have been obvious to modify the transponder of Yoakum to include endcaps having the same cross-sectional dimension as taught by Taylor, and that the modified transponders would be suitable for encapsulation in the molding tool 40 of Yoakum. The Examiner's characterization of Taylor, however, is inaccurate. For example, the Examiner alleges that "[t]he endcaps [70b] of Fig. 8B of Taylor have [the] same cross-section[al] diameter as the center portion with the coil [70a] and capacitor 54." (Office Action, p. 15.) This is not correct. Taylor specifically discloses that the coil 70a is generally cylindrical and includes a center section "of reduced cross-sectional dimension and larger end members 70b." (Taylor, col. 8, lns. 19-23; emphasis added.) Accordingly, Taylor does not disclose or suggest endcaps having the same cross-sectional diameter as the coil and, as discussed above, the enlarge endcaps of Taylor would likely interfere with the placement of the transponder in Yoakum's molding tool.

The M.P.E.P. states that "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggest the desirability of the combination." (M.P.E.P. § 2143.01; emphasis added.) Here, the prior art does not suggest the desirability of the combination and, in fact, teaches away from the combination proposed by the Examiner because Yoakum specifically teaches a molding tool 40 to encapsulate the transponder that does not include endcaps. Accordingly, the Section 103 rejection of claim 22 should be withdrawn.

I. Response to the Section 103 Rejection of Claim 19 (Mejia and Hansen)

Claim 19 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Mejia in view of Hansen.

1. Independent Claim 19 is Directed to a Miniature Resonating Marker Assembly Having a Core with a First Cap Having a First Thickness and a Second Cap Having a Second Thickness, the First Cap Being Movable Relative to a Coil to Tune the Marker Assembly to a Selected Inductance Value

Independent claim 19 is directed to a miniature resonating marker assembly. The miniature resonating marker assembly includes a core with an elongated central portion and two enlarged caps attached to the central portion. The first cap has an axial thickness different than the axial thickness of the second cap. A wire coil is disposed around the central portion of the core between the first and second caps, and a capacitor is connected to the coil adjacent to the core to form a signal element tuned to a selected resonant frequency. The first cap is movable relative to the coil and capacitor to tune the marker assembly to have a selected inductance value.

2. Claim 19 is Patentable Over Mejia and Hansen Because the Applied References Fail to Disclose or Suggest a First Cap Being Movable Relative to the Coil and Capacitor for Tuning the Marker Assembly

Claim 19 is patentable over Mejia and Hansen under Section 103 because these references fail to disclose or suggest "a first cap being movable relative to the coil and capacitor for tuning the marker assembly to a selected resonant frequency." As discussed previously, however, Mejia teaches a unitary core 12 having a coil forming portion 16 and an IC support portion 18. The core 12 in Mejia is not movable relative to the coil 20 or the capacitor 28, and the core 12 does not appear to have any moveable components. Furthermore, as discussed above, Hansen does not teach or suggest a core having more than one adjustable segment or portion. The rod 11 of Hansen is movable relative to the coil 13; however, Hansen's rod 11 is a single, unitary member and does not include a cap movable relative to the coil 13 and/or capacitor 15 for tuning the marker assembly. Accordingly, the combination of Mejia and Hansen does not teach or suggest all the claimed features and, therefore, the Section 103 rejection of claim 19 should be withdrawn.

J. Response to the Section 103 Rejection of Claim 25 (Lemberger and Taylor)

Claim 25 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Lemberger in view of Taylor.

1. Independent Claim 25 is Directed to a Resonating Marker Assembly Having a Core with a First Magnetic Permeability and Enlarged Endcaps Having a Second Magnetic Permeability Different than the First Magnetic Permeability

Independent claim 25 is directed to a resonating marker assembly. The resonating marker assembly includes a core having a central portion intermediate to a pair of enlarged endcaps. The central portion of the core has a first magnetic permeability and the enlarged endcaps have a second magnetic permeability different than the first magnetic permeability. A wire coil is disposed around the core intermediate to the endcaps, and a capacitor is operatively connected to the coil to form a signal element that generates a magnetic field with a selected resonant frequency in response to a specific stimulus. The resonating marker assembly also includes an inert encapsulation member encapsulating the core, the wire coil, and the capacitor to form an activatable unit implantable in a patient through an introducer needle.

2. Claim 25 is Patentable Over Lemberger and Taylor Because the Applied References Fail to Disclose or Suggest a First Cap Being Movable Relative to the Coil and Capacitor for Tuning the Marker Assembly

Claim 25 is patentable over Lemberger and Taylor because these references fail to teach a core having a central portion with "a first magnetic permeability" and enlarged endcaps with "a second magnetic permeability different than the first magnetic permeability." The Examiner correctly notes that Lemberger "does not disclose a pair of enlarged endcaps having different magnetic permeability." (Office Action, p. 11.) The Examiner incorrectly asserts, however, that it would have been obvious to provide enlarged endcaps to the core of Lemberger in accordance with the teachings of Taylor,

and that it is merely a matter of design choice to have the core and endcaps made from different material. (*Id.*)

The proper legal standard for a *prima facie* obviousness rejection includes, *inter alia*, whether the teaching and suggestion to make the claimed combination and the reasonable expectation of success are both found in the prior art, and not in the applicant's disclosure. (M.P.E.P. § 2143.) Here, the Examiner fails to identify where the prior art teaches or suggests making the claimed combination. Instead, the Examiner improperly creates a new standard that is based upon alleged beneficial results that could result from a combination of the references without regard for the teachings of the references.

The Examiner's unsupported conclusion to combine these two references is based solely on the alleged beneficial results that the Examiner asserts would result from combining them and goes against the teachings of the references. The Examiner asserts that modifying Lemberger's projectile 10 to include enlarged endcaps would provide "a more accurate resonating marker assembly due to the firm position of the coil over the core by the enlarged endcaps." (Office Action, p. 11.) Such a modification to Lemberger's projectiles, however, would make the devices significantly more complicated to construct and, thus, significantly more expensive. The projectiles of Lemberger and the transponders of Taylor are used in animals. There is no need for accuracy in the devices as they are merely used to identify an animal; they are not used to determine the particular location or region of the animal where the device is implanted.

In contrast to the devices of Lemberger and Taylor, the claimed marker assembly is for use in human patients to precisely identify a specific region where the device is implanted. Highly accurate and sensitive components are required for such devices. Thus, there is no teaching or suggestion in the applied references to modify the crude marking devices of Lemberger and Taylor to include the complex combination and arrangement of features in the claimed marker assembly. Thus, regardless of what the Examiner believes one of ordinary skill would conclude with hindsight of Applicant's disclosure, the Examiner has failed to identify where the prior art teaches or suggests

making the claimed combination. Accordingly, the Section 103 rejection of claim 25 should be withdrawn.

VIII. CLAIMS

A copy of the claims involved in the present appeal is attached hereto as Appendix A.

IX. EVIDENCE

No evidence pursuant to §§ 1.130, 1.131, or 1.132 or entered by or relied upon by the Examiner is being submitted.

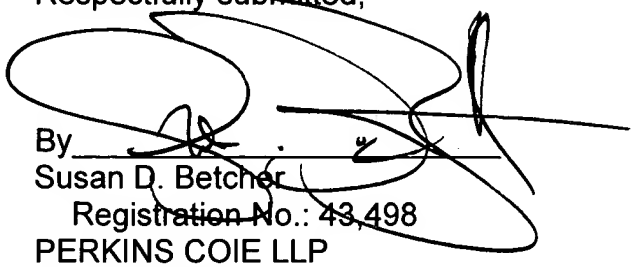
X. RELATED PROCEEDINGS

No are no related proceedings.

Dated:

1/4/06

Respectfully submitted,



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APPENDIX A

Claims Involved in the Appeal of Application Serial No. 09/954,700

1. (Previously presented) A miniature resonating marker assembly, comprising

a signal element comprising a core, a wire coil disposed around the core, and a capacitor connected to the wire coil, the signal element generating a magnetic field with a selected resonant frequency in response to a specific stimulus, and the magnetic field having a magnetic center along a first axis of the core; and

an inert encapsulation member encapsulating the signal element, the encapsulation member and the signal element therein defining a unit having a selected geometric shape having a geometric center, the geometric center being coincident with the magnetic center along at least the first axis of the core.

2. (Original) The miniature resonating marker assembly of claim 1 wherein the core is a material with a relative permeability greater than 1.0.

3. (Original) The miniature resonating marker assembly of claim 1 wherein the core is a ferromagnetic core.

4. (Original) The miniature resonating marker assembly of claim 1 wherein the core has a rod portion positioned within the coil and a pair of enlarged ferromagnetic endcaps connected to the rod portion, the endcaps having a relative permeability greater than 1, the coil being disposed between the endcaps.

5. (Original) The miniature resonating marker assembly of claim 4 wherein the endcaps are made of a ferromagnetic material.

6. (Original) The miniature resonating marker assembly of claim 4 wherein the endcaps each have an arcuate outer surface facing away from the rod portion.

7. (Original) The miniature resonating marker assembly of claim 1 wherein the core has a rod portion positioned within the coil and a pair of enlarged endcaps connected to the rod, the coil being disposed between the endcaps, one of the endcaps having a volume of material greater than the volume of material of the other endcap.

8. (Original) The miniature resonating marker assembly of claim 1 wherein the ferromagnetic core extends through the coil and has a first end portion exterior of one end of the coil and a second end portion exterior of another end of the coil, the first end portion exterior of the coil having a volume greater than the volume of the second end portion so the magnetic center is spaced apart from a center point of the coil.

9. (Original) The miniature resonating marker assembly of claim 1 wherein the core has a rod portion positioned in the coil, a first endcap connected to one end portion of the rod portion, and a second endcap connected to another end portion of the rod, the first endcap being larger than the second endcap.

10. (Previously presented) The miniature resonating marker assembly of claim 1 wherein the core has a rod portion positioned in the coil, a first endcap connected to an end portion of the rod portion, and a second endcap connected to another end portion of the rod portion, the first endcap being axially adjustable over the rod portion and relative to the coil.

11. (Original) The miniature resonating marker assembly of claim 10 wherein second endcap is fixed relative to the rod portion.

12. (Previously presented) The miniature resonating marker assembly of claim 1 wherein the geometric center is coincident with the magnetic center along three axes of the unit.

13. (Previously presented) The miniature resonating marker assembly of claim 1, further comprising a sleeve positioned between the wire coil and the core, the wire coil being wound onto the sleeve, and the sleeve and coil being positioned over the core.

14. (Original) The miniature resonating marker assembly of claim 13 wherein the core is disposed within the sleeve and axially movable relative to the coil to achieve a selected resonant frequency of the assembly.

15. (Previously presented) The miniature resonating marker assembly of claim 1, further comprising a ferromagnetic adhesive securely retaining the coil on the core.

16. (Original) The miniature resonating marker assembly of claim 1 wherein the wire coil includes a plurality of windings of a wire, the wire having a bonding coating thereon to adhere the wire of one wind to the wire of an adjacent wind.

17. (Previously presented) The miniature resonating marker assembly of claim 1 wherein the unit is attached to an anchoring member extending from one end of the unit, and the anchoring member is shaped to anchor the unit to tissue in or on a patient.

18. (Original) The miniature resonating marker assembly of claim 1 wherein the assembly has an axial length of approximately 14 mm or less.

19. (Previously presented) A miniature resonating marker assembly having a geometric center, comprising:

a core having an elongated central portion, a first cap having a first thickness, and a second cap having a second thickness, wherein the first thickness is different than the second thickness;

a wire coil disposed around the central portion of the core between the first and second caps; and

a capacitor connected to the wire coil operative to form a signal element that generates a magnetic field with a selected resonant frequency in response to a specific stimulus, the first cap being movable relative to the coil and capacitor for tuning the marker assembly to a selected resonant frequency.

20. (Previously presented) A resonating marker assembly having a geometric center, comprising:

a ferromagnetic core having an elongated central portion and first and second ferromagnetic endcaps at opposite ends of the central portion, the core being substantially symmetrical about a longitudinal axis of the core, and being asymmetrical about a lateral axis of the core;

a wire coil disposed around the central portion of the ferromagnetic core intermediate the first and second endcaps; and

a capacitor connected to the wire coil forming a signal element that generates a magnetic field with a selected resonant frequency in response to a specific stimulus, the magnetic field having a magnetic center along a first axis coincident with the geometric center of the resonating marker assembly.

21. (Previously presented) A resonating marker assembly having a geometric center, comprising:

a core having an elongated central portion and first and second endcaps connected to the central portion;

a wire coil disposed around the central portion of core intermediate the first and second endcaps; and

a capacitor connected to the wire coil to form a tuned signal element that generates a magnetic field with a selected resonant frequency in response to a specific stimulus, the first endcap being movable relative to the coil and capacitor for tuning the marker assembly to a selected resonant frequency.

22. (Previously presented) A resonating marker assembly, comprising:

a sleeve;

a core having a central portion extending through the sleeve and a pair of endcaps connected to the central portion, the sleeve being between the endcaps, and the core being axially movable relative to the sleeve;

a wire coil disposed around the sleeve; and

a capacitor connected to the wire coil proximate to the core to form a signal element that generates a magnetic field with a selected resonant frequency in response to a specific stimulus, the core being axially movable relative to the sleeve and the coil for tuning the marker assembly to a selected resonant frequency.

23. (Withdrawn) A tunable, resonating marker assembly, comprising:

a wire coil defining an interior area;

a capacitor connected to the wire coil to form an electrical circuit; and

a ferromagnetic core having first and second segments each extending at least partially into the interior area of the coil, the first and second segments being axially movable relative to each other and to the coil for tuning the marker assembly to a selected resonant frequency.

24. (Previously presented) A resonating marker assembly, comprising:

a ferromagnetic core having a first end and a second end;

a wire coil disposed around the ferromagnetic core;

a capacitor positioned at the first end of the core and operatively connected to the wire coil to form a signal element that generates a magnetic field with a selected resonant frequency in response to a specific stimulus; and

an axially adjustable segment at the second end of the core that projects outwardly with respect to the longitudinal axis of the core.

25. (Previously presented) A resonating marker assembly, comprising:

a core having a central portion intermediate to a pair of enlarged endcaps, the central portion having a first magnetic permeability and the enlarged endcaps having a second magnetic permeability different than the first magnetic permeability;

a wire coil disposed around the core intermediate to the endcaps;

a capacitor operatively connected to the wire coil to form a signal element that generates a magnetic field with a selected resonant frequency in response to a specific stimulus; and

an inert encapsulation member encapsulating the core, the wire coil, and the capacitor forming an activatable unit implantable in a patient through an introducer needle.

26. (Original) A resonating marker assembly, comprising;

a capacitor having an aperture therethrough;

an elongated ferromagnetic core extending through the aperture in the capacitor;

a wire coil connected to the capacitor, the wire coil having a first portion disposed around the core adjacent to one side of the capacitor, and a second portion disposed around the core adjacent to another side of the capacitor; and

an inert encapsulation member encapsulating the capacitor, the core, and the coil.

27. (Withdrawn) A resonating marker assembly, comprising:

an elongated core having an I-shaped cross-sectional area defined by a central web portion intermediate a pair of flange portions connected to the central web portion;

a wire coil disposed around the central web portion between the flange portions of the core;

a capacitor connected to the wire coil adjacent to the core to form a signal element that generates a magnetic field with a selected resonant frequency in response to a specific stimulus; and

an inert encapsulation member encapsulating the signal element forming an inert implantable, activatable marker assembly.

28-39. (Cancelled)